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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,562	03/01/2004	Abraham Bout	2578-4038.3US	9903

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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,562	BOUT ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-21 and 25-56* is/are pending in the application.

4a) Of the above claim(s) *21,25-29 and 42-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-20 and 30-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004 and 27 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 10/31/2006 in which claims 22-24 were cancelled, claims 9 and 11-15 were amended, and claims 31-56 were added. Claims 1, 7-21 and 25-56 are pending. Claims 21, 25-29 and 42-56 are withdrawn. Claims 1, 7-20 and 30-41 are under examination in the instant Office action.

Any rejection set forth in the previous Office action not recited herein is hereby withdrawn.

Election/Restrictions

Newly submitted claims 42-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 42-56 are drawn to a method for recombinant protein production and would have been grouped with the non-elected Group II invention in the restriction requirement sent 11/3/2005 had they been previously presented.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 42-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 21, 25-29 and 42-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/23/2005.

Information Disclosure Statement

The IDS submitted 10/31/2006 has been considered and an initialed and signed copy is attached.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 9, 20 & 41, and therefore dependent claims 8, 10-19 & 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant

regards as the invention. **These are new rejections, some of which were not necessitated by Applicant's amendment.**

Claim 1 recites "wherein the eukaryotic cell is of a human embryonic retinoblast origin" in line 11 (emphasis added). Claim 1 is vague and indefinite in that the metes and bounds of a cell which is "of a human embryonic retinoblast origin" are unclear. Does Applicant intend a cell which was previously of a human embryonic retinoblast origin but has evolved or transformed into some other kind of cell, or does Applicant intend such a cell wherein the cell is a human embryonic retinoblast cell?

Claim 7 recites "[t]he eukaryotic cell of claim 1, wherein the first and second nucleotide sequence encoding the adenoviral E1A and E1B proteins are integrated in the genome of the eukaryotic cell and are derived from nucleotides 459-3510 (SEQ ID NO:33) of an adenovirus 5 genome" in lines 1-4 (emphasis added). Claim 7 is vague and indefinite in that the metes and bounds of a nucleotide sequence which is "derived from" nucleotides 459-3510 (SEQ ID NO:33) of an adenovirus genome are unclear because the steps and structural changes involved in the deriving are unknown.

Claim 9 recites "[t]he eukaryotic cell of claim 1, wherein the eukaryotic cell is of a cell as deposited under ECACC no.

96022940 origin" in lines 1-2 (emphasis added). Claim 9 is vague and indefinite because the metes and bounds of a cell "of a cell as deposited under ECACC no. 96022940 origin" are unclear. Does Applicant intend a eukaryotic cell as deposited under ECACC no. 96022940, or does Applicant intend a eukaryotic cell which began as a cell as deposited under ECACC no. 96022940 but was then modified or otherwise allowed to change such that the cell is now only of such origin?

Claim 20 recites "[t]he cell culture of claim 18, wherein the suitable medium is free of animal- or human-derived serum and animal- or human-derived serum components" in lines 1-3 (emphasis added). Claim 20 is vague and indefinite in that the metes and bounds of "animal- or human-derived serum and animal- and human-derived serum components" are unclear because the steps and structures involved in the "deriving" are unknown. Does Applicant intend serum/serum components from an animal or human, or does Applicant intend serum/serum components from animal or human serum but which have been altered in some way?

Similarly, claim 41 recites "[t]he cell culture of claim 39, wherein the suitable medium is free of animal- or human-derived serum and animal- or human-derived serum components" in lines 1-3 (emphasis added). Claim 41 is also vague and indefinite in that the metes and bounds of "animal- or human-

derived serum and animal- and human-derived serum components" are unclear because the steps and structures involved in the "deriving" are unknown. Does Applicant intend serum/serum components from an animal or human, or does Applicant intend serum/serum components from animal or human serum but which have been altered in some way?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-9, 11-13, 17-18, 32-34 and 38-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25 and 30 of copending Application No. 10/499,298. **This provisional rejection is maintained for reasons of record.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 7-9, 11-13, 17-18, 32-34 and 38-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-50 and 89-90 of copending Application No. 11/593,279. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to PER-C6 cells which produce a heterologous immunoglobulin, variable domain of an antibody or an antibody itself. **This is a new rejection.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 7-9, 11-13, 17-18, 32-34 and 38-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-50 and 89-90 of copending Application No. 11/593,280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to PER-C6 cells which produce a heterologous immunoglobulin, variable domain of an antibody or an antibody itself. **This is a new rejection.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 7-9, 15-16 and 36-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-32 of copending Application No. 11/593,280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to PER-C6 cells which produce heterologous viral proteins. **This is a new rejection.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Receipt is acknowledged of the terminal disclaimer filed 10/31/2006. The terminal disclaimer is found ineffective with regard to overcoming the double patenting rejection over U.S. Patent Application 10/499,298 because the terminal disclaimer recites Patent No. 6,855,544 only. The terminal disclaimer does not recite and, therefore, does not apply to application number 10/499,298. Thus, the provisional rejection(s) on the grounds of nonstatutory double patenting cited above are maintained.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

January 15, 2007

NANCY VOGEL
PRIMARY EXAMINER